REMARKS

Claims 1 – 7, 9, 10 and 16 – 20 are currently pending, with Claims 6, 7, 9, and 10 having been withdrawn from consideration and Claims 1 – 5 and 16 – 19 having been considered on the merits. In the Office Action, Claims 1 – 5 and 16 – 19 were rejected under Section 103 as allegedly obvious over the Miyazawa publication taken in combination with U.S. Patent No. 6,395,300 to Straub. No other grounds of objection or rejection were raised.

Each of the foregoing rejections is respectfully traversed. Favorable reconsideration is requested in view of the above amendments and following remarks.

I. The Obviousness Rejections.

The Examiner again asserts that Claims 1 – 5 and 16 – 19 are obvious over Miyazawa taken with Straub. As the Applicants have stressed before however, each of these claims specifically recites tamsulosin hydrochloride in amorphous form. This is neither disclosed nor suggested by the cited references.

Miyazawa discloses very non-specific "porous drug matrices and methods of manufacture thereof." Miyazawa includes an extensive list of potential so-called "preferable" drugs that are contemplated—found at the bottom of Column 7 and including well over 100 drugs. However, Miyazawa says nothing about the preparation of amorphous tamsulosin hydrochloride. In fact, Miyazawa gives no specific examples or any suggestion whatsoever that an amorphous form of tamsulosin hydrochloride even exists.

Nonetheless, the Examiner asserts an amorphous form of tamsulosin would have been obvious from Straub since, in the Examiner's view, Straub allegedly "discloses a method for producing drugs in a crystalline state, an amorphous state, ***or*** mixtures thereof ... wherein the drugs include tamsulosin hydrochloride."

The Applicants respectfully disagree. Straub does not disclose or suggest the existence of tamsulosin hydrochloride in amorphous form. Straub is generally directed to porous matrices said to provide enhanced dissolution of drugs. At columns 4 – 8, Straub lists scores of active ingredients which may be used in the practice of his technology and, at column 12, lines 42 – 45, Straub states that some of these drugs may be present in a crystalline form and some in the amorphous form. However, Straub says nothing whatsoever about the existence of tamsulosin hydrochloride in amorphous form. The Examiner simply overstates the teachings of Straub.

Straub also plainly does not instruct or even suggest those of skill in the art how to make tamsulosin hydrochloride in the amorphous form. "Although published subject matter is "prior art" for all that it discloses, in order to render an invention unpatentable for obviousness, the prior art must enable a person of ordinary skill to make and use the invention." *See In re Kumar*, 418 F.3d 1361 (Fed. Cir. 2005). Here, Straub falls very short of such burden.

Moreover, Claim 1 specifies that the amorphous tamsulosin hydrochloride is prepared by the lyophilization of tamsulosin hydrochloride from a solution, as opposed to an emulsion or other mixture. More preferably, the amorphous tamsulosin hydrochloride is prepared by lyophilization of tamsulosin hydrochloride from an aqueous solution.

This is contrary to the teachings of the Straub patent, which teaches lyophilization from a mixture comprising both a solvent and an additive which is referred to as a "pore forming agent." According to Straub, the pore forming agent is preferably a liquid which is immiscible with the solvent (Col. 10 Line 59 – 67). Thus an emulsion is formed and tamsulosin hydrochloride is lyophilized from this emulsion rather than a solution. A stabilizer such as a surfactant may also be included in the emulsion. (Col. 12 Line 47 – 50) Alternatively a solid pore forming agent may be used but this agent may also lead to the formation of an emulsion with the solvent or the solid agent may exist as solid particulates in the solvent (Col. 11 Line 13 – 18). Here again, tamsulosin hydrochloride is not lyophilized from a simple solution.

The addition of these additives is significant because their presence is likely to alter the morphology of the tamsulosin hydrochloride produced by the lyophilization process. In other words, the additional presence of the pore forming agents may well lead to formation of a crystalline tamsulosin hydrochloride product, rather than an amorphous product.

Thus, the subject matter of independent Claim 1 (as well as its dependent claims) is patentable over the cited art.

II. New Claim 20.

In addition, the Applicants have added new Claim 20 to the case. Claim 20 depends from Claim 1 and includes all the limitations thereof. Thus, all of the foregoing remarks are also applicable to Claim 20, and Claim 20 distinguishes over the prior art for at least the same reasons as Claim 1.

Moreover, Claim 20 further specifies that the amorphous tamsulosin hydrochloride of Claim 1 is at least 75% pure. In other words, at least 75% of the tamsulosin hydrochloride, prepared by the lyophilization defined in Claim 1, is amorphous. This is certainly not disclose or suggested by the cited combination of Miyazawa with Straub. Even if Miyazawa with Straub suggested a process which might lead to some amount of amorphous tamsulosin hydrochloride (which they do not), there is still nothing in the two references to suggest an amorphous tamsulosin hydrochloride having a purity of at least 75%.

Thus, Claim 20 separately distinguishes over the cited references for at least this reason, over and above the reason previously set forth with respect to Claim 1.

In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a notice of allowance at the earliest possible convenience.

Respectfully submitted,

By: /J. David Gonce/

J. David Gonce
Registration No. 47,601

JDG:lal

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P.O. Box 1871
Knoxville, Tennessee 37901
865-546-4305